

## Ipsen delivers strong double-digit sales growth for the third quarter of 2019 and confirms full year 2019 guidance

Paris (France), 24 October 2019 – Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group, today announced sales for the third quarter of 2019.

### Financial highlights

- Q3 2019 Group sales growth of +16.0% as reported and +14.5%<sup>1</sup> at constant exchange rates and consolidation scope, driven by Specialty Care sales growth of 16.5%<sup>1</sup>, reflecting strong double-digit momentum of Somatuline® (lanreotide) and the continued growth from Cabometyx® (cabozantinib) and Decapeptyl® (triptorelin)
- YTD Group sales growth of +15.7% as reported and +14.3%<sup>1</sup> at constant exchange rates and consolidation scope fueled by strong Specialty Care sales growth of 16.8%<sup>1</sup>
- Full Year 2019 guidance confirmed with Group sales growth greater than +14.0% at constant currency and consolidation scope<sup>1</sup> and Core Operating margin at around 30.0% of net sales

### Recent pipeline highlights

- Positive interim Phase 1/2 clinical data evaluating Onivyde® (liposomal irinotecan) as first-line treatment for metastatic pancreatic cancer presented at ESMO 21st World Congress on Gastrointestinal Cancer
- Positive interim data from seamless Phase 2/3 clinical trial evaluating Onivyde as a second-line treatment for small cell lung cancer (SCLC) presented at the IASLC 2019 World Conference on Lung Cancer
- FDA approval of Dysport® (abobotulinumtoxinA) for the treatment of upper limb spasticity in children two years of age and older, excluding spasticity caused by cerebral palsy (CP)
- In-licensing of BLU-782 from Blueprint Medicines, a highly selective ALK2 inhibitor in Phase 1 development for the treatment of fibrodysplasia ossificans progressiva (FOP)
- Palovarotene regulatory submission to the FDA for the episodic treatment of FOP now expected in Q1 2020 as a result of the processing of additional supportive data.

### Key figures

Unaudited IFRS consolidated sales

(in million euros)	Third Quarter				Nine Months			
	2019	2018	% Variation	% Variation at constant currency and consolidation scope <sup>1</sup>	2019	2018	% Variation	% Variation at constant currency and consolidation scope <sup>1</sup>
Specialty Care	574.2	484.1	18.6%	16.5%	1,674.1	1,404.2	19.2%	16.8%
Consumer Healthcare	70.6	71.9	-1.8%	0.1%	200.2	216.2	-7.4%	-2.4%
<b>Group sales</b>	<b>644.7</b>	<b>555.9</b>	<b>16.0%</b>	<b>14.5%</b>	<b>1,874.3</b>	<b>1,620.4</b>	<b>15.7%</b>	<b>14.3%</b>

<sup>1</sup> Subsidiaries involved in the partnership between Ipsen and Schwabe Group are consolidated in accordance with the equity method starting 1 January, 2019. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.

**David Meek, Chief Executive Officer of Ipsen** stated: “In the third quarter, we continued to execute on our objectives with a strong performance of our Specialty Care business, including double-digit growth of Somatuline in both the U.S. and Europe. With our excellent performance year-to-date, we are increasingly confident in our ability to achieve our 2019 financial guidance.

“We remain focused on the successful execution of the palovarotene program to bring the first therapeutic treatment to FOP patients as expeditiously as possible. We also continue to deliver on our external innovation strategy. The recent in-licensing of BLU-782 reinforces our leadership in FOP with a different and potentially complementary mechanism of action to palovarotene, expands our portfolio approach in this complex ultra-rare bone disorder and leverages our clinical and commercial capabilities. Advancing our pipeline remains a key focus going forward to deliver on our growth strategy and to bring additional value to patients and shareholders.”

### **Third quarter 2019 sales highlights**

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts (currency effects established by recalculating net sales for the relevant period at the exchange rates from the previous period)

(in million euros)	2019	2018	% Variation	% Variation at constant currency and consolidation scope <sup>1</sup>
<b>Specialty Care</b>	<b>574.2</b>	<b>484.1</b>	<b>18.6%</b>	<b>16.5%</b>
Somatuline®	264.0	217.0	21.7%	18.8%
Decapeptyl®	98.9	89.2	10.9%	10.5%
Cabometyx®	64.5	38.8	66.5%	66.3%
Onivyde®	26.1	26.9	-3.0%	-7.3%
Dysport®	97.4	87.7	11.0%	8.8%
<b>Consumer Healthcare</b>	<b>70.6</b>	<b>71.9</b>	<b>-1.8%</b>	<b>0.1%</b>
Smecta®	34.1	32.8	4.1%	2.5%
Forlax®	10.5	9.5	10.6%	9.7%
Tanakan®	8.8	9.6	-8.8%	-10.0%
<b>Group sales</b>	<b>644.7</b>	<b>555.9</b>	<b>16.0%</b>	<b>14.5%</b>

**Q3 2019 Group sales** grew 14.5%<sup>1</sup> to €644.7 million.

Sales of **Specialty Care** products reached €574.2 million, up 16.5% year-on-year.

**Somatuline** sales reached €264.0 million, up 18.8%, year-on-year, driven by 20.0% growth in North America, double-digit growth in key European countries and good performance in Japan.

**Decapeptyl** sales reached €98.9 million, up 10.5% year-on-year, driven by volume and market share gains in Europe and double-digit growth in China.

**Cabometyx** sales reached €64.5 million, growing 66.3% year-on-year, driven by the good performance in all launched European countries and additional launches in Asia and Oceania.

**Onivyde** sales reached €26.1 million, down 7.3% year-on-year, impacted by limited shipments to Ipsen’s ex-U.S. partner in the third quarter.

**Dysport** sales reached €97.4 million, up 8.8% year-on-year, driven by the solid performance in the U.S. in the therapeutics and aesthetics markets, as well as growth from Galderma in Europe.

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**Consumer Healthcare** product sales totaled €70.6 million, stable at +0.1%<sup>1</sup>, driven by Smecta growth of 2.5% year-on-year, from the good performance in France and in China despite the new hospital competitive pricing environment, and Forlax growth of 9.7% year-on-year. Tanakan sales reached €8.8 million, down 10.0% year-on-year, due to competitive pressure in emerging countries and a market slowdown in France.

### **Confirmation of Full Year 2019 guidance**

- **Group sales growth greater than +14.0%** at constant currency and consolidation scope<sup>1</sup>
  - Impact of currencies estimated at +2.0% based on the current level of exchange rates
  - Impact of consolidation scope reflecting the consolidation under the equity method for joint arrangements related to the Schwabe partnership estimated at -1.0%
- **Core Operating margin at around 30.0% of net sales**

### **Conference call**

Ipsen will hold a conference call Thursday, 24 October 2019 at 2:30 p.m. (Paris time, GMT+2). Participants should dial in to the call approximately five to ten minutes prior to its start. No reservation is required to participate in the conference call.

Standard International: +44 (0) 2071-928-000  
France and continental Europe: +33 (0) 1 76 70 07 94  
UK: 08-445-718-892  
U.S.: 1-6315-107-495  
Conference ID: 5649858

A recording will be available for seven days on Ipsen's website.

### **About Ipsen**

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and Specialty Care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neuroscience and Rare Diseases. Its commitment to Oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €2.2billion in 2018, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,700 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit [www.ipsen.com](http://www.ipsen.com).

### **Forward Looking Statement**

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes", "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favorable results obtained during pre-clinical

trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2018 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

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## Comparison of Consolidated Sales for the Third Quarter and First nine months of 2019 and 2018:

All variations in sales are stated excluding foreign exchange impacts, established by recalculating net sales for the relevant period at the rates from the previous period.

Subsidiaries involved in the partnership between Ipsen and Schwabe Group are consolidated in accordance with the equity method starting 1 January, 2019. Group and Consumer Healthcare variations in sales presented below are restated to exclude 2018 sales from the Schwabe partnership.

### Sales by therapeutic area and by product

(in million euros)	3 <sup>rd</sup> Quarter				9 Months			
	2019	2018	% Variation	% Variation at constant currency and consolidation scope <sup>1</sup>	2019	2018	% Variation	% Variation at constant currency and consolidation scope <sup>1</sup>
<b>Oncology</b>	<b>460.1</b>	<b>378.7</b>	<b>21.5%</b>	<b>19.5%</b>	<b>1,339.2</b>	<b>1,088.4</b>	<b>23.0%</b>	<b>20.3%</b>
Somatuline®	264.0	217.0	21.7%	18.8%	742.9	619.5	19.9%	16.2%
Decapeptyl®	98.9	89.2	10.9%	10.5%	297.3	272.5	9.1%	8.8%
Cabometyx®	64.5	38.8	66.5%	66.3%	176.3	100.8	75.0%	74.9%
Onivyde®	26.1	26.9	-3.0%	-7.3%	100.5	75.8	32.6%	24.7%
Other Oncology	6.5	6.8	-4.0%	-4.0%	22.1	19.8	11.9%	11.6%
<b>Neuroscience</b>	<b>98.0</b>	<b>88.3</b>	<b>11.1%</b>	<b>8.8%</b>	<b>285.8</b>	<b>262.8</b>	<b>8.7%</b>	<b>7.3%</b>
Dysport®	97.4	87.7	11.0%	8.8%	283.6	260.5	8.9%	7.4%
<b>Rare Diseases</b>	<b>16.0</b>	<b>17.1</b>	<b>-6.3%</b>	<b>-7.2%</b>	<b>49.2</b>	<b>53.1</b>	<b>-7.4%</b>	<b>-8.7%</b>
NutropinAq®	10.2	11.3	-9.2%	-9.0%	32.1	35.4	-9.3%	-9.2%
Increlex®	5.8	5.9	-1.0%	-3.7%	17.1	17.7	-3.5%	-7.6%
<b>Specialty Care</b>	<b>574.2</b>	<b>484.1</b>	<b>18.6%</b>	<b>16.5%</b>	<b>1,674.1</b>	<b>1,404.2</b>	<b>19.2%</b>	<b>16.8%</b>
Smecta®	34.1	32.8	4.1%	2.5%	92.0	95.2	-3.4%	-4.2%
Forlax®	10.5	9.5	10.6%	9.7%	29.5	28.6	3.3%	2.9%
Tanakan®	8.8	9.6	-8.8%	-10.0%	26.4	25.5	3.4%	3.0%
Fortrans/Eziclen®	8.3	8.1	3.1%	1.5%	25.1	22.1	13.6%	12.9%
Other Consumer Healthcare	8.8	11.9	-25.9%	-8.5%	27.2	44.8	-24.3%	-17.0%
<b>Consumer Healthcare</b>	<b>70.6</b>	<b>71.9</b>	<b>-1.8%</b>	<b>0.1%</b>	<b>200.2</b>	<b>216.2</b>	<b>-7.4%</b>	<b>-2.4%</b>
<b>Group Sales</b>	<b>644.7</b>	<b>555.9</b>	<b>16.0%</b>	<b>14.5%</b>	<b>1,874.3</b>	<b>1,620.4</b>	<b>15.7%</b>	<b>14.3%</b>

In the first nine months of 2019, Group sales reached €1,874.3 million, up 14.3%<sup>1</sup>, driven by Specialty Care sales growth of 16.8%, while Consumer Healthcare sales decreased by 2.4%<sup>1</sup>.

Specialty Care sales amounted to €1,674.1 million, up 16.8%. Oncology and Neuroscience sales grew by 20.3% and 7.3%, respectively, while Rare Diseases sales decreased by 8.7%. Over the period, the relative weight of Specialty Care continued to increase to reach 89.3% of total Group sales, compared to 86.7% in 2018.

<sup>1</sup> Subsidiaries involved in the partnership between Ipsen and Schwabe Group are consolidated in accordance with the equity method starting 1 January, 2019. Year-on-year growth excluding foreign exchange impact established by recalculating net sales for the relevant period at the rate used for the previous period.

In **Oncology**, sales reached €1,339.2 million, up 20.3% year-on-year, driven by continued strong performance across major products and geographies. Over the period, Oncology sales represented 71.5% of total Group sales, compared to 67.2% in 2018.

**Somatuline** – Sales reached €742.9 million, up 16.2% year-on-year, driven by 19.8% growth in North America primarily from volume growth, as well as by continued double-digit growth in Europe.

**Decapeptyl** – Sales reached €297.3 million, up 8.8% year-on-year, driven mainly by volume growth in Major Western European countries, good sales performance in China and by higher sales in Asia, Middle East and Latin America.

**Cabometyx** – Sales reached €176.3 million, up 74.9% year-on-year, driven by good performance in all European countries, as well as launches in Canada and in several countries in Asia and Oceania.

**Onivyde** – Sales reached €100.5 million, up 24.7% year on year, including steady growing demand in the U.S. and higher sales to Ipsen's ex-U.S. partner.

In **Neuroscience**, sales of **Dysport** reached €283.6 million, up 7.4%, driven by the good performance in the U.S. and in Europe in the therapeutics and aesthetics markets. Over the period, Neuroscience sales represented 15.2% of total Group sales, compared to 16.2% in 2018.

In **Rare Diseases**, sales of **NutropinAq** reached €32.1 million, down 9.2% year-on-year, impacted by lower volumes across Europe. Sales of **Increlex** reached €17.1 million, down 7.6% year-on-year mainly due to lower demand in the U.S. Over the period, Rare Diseases sales represented 2.6% of total Group sales, compared to 3.3% in 2018.

**Consumer Healthcare** sales reached €200.2 million, down 2.4%, impacted by a decline in Smecta sales of 4.2% year-on-year mainly due to the new hospital competitive environment in China and lower performance in Algeria. Fortrans/Eziclen sales were up 12.9% year-on-year driven by China. Tanakan year-on-year growth reached 3.0%, due to the low 2018 Vietnam baseline and the good performance in Russia. Over the period, Consumer Healthcare sales represented 10.7% of total Group sales, compared to 13.3% in 2018.

## Sales by geographical area

(in million euros)	3 <sup>rd</sup> Quarter				9 Months			
	2019	2018	% Variation	% Variation at constant currency and consolidation scope <sup>1</sup>	2019	2018	% Variation	% Variation at constant currency and consolidation scope <sup>1</sup>
France	71.2	67.5	5.5%	5.6%	240.1	201.2	19.3%	18.7%
Germany	47.1	42.0	12.2%	18.4%	141.7	133.0	6.5%	17.4%
Italy	27.8	25.5	9.2%	9.2%	87.8	78.6	11.7%	11.7%
Spain	26.3	22.3	17.7%	17.7%	77.1	66.3	16.2%	16.2%
United Kingdom	25.3	24.0	5.5%	6.8%	75.9	70.5	7.6%	7.5%
<b>Major Western European countries</b>	<b>197.8</b>	<b>181.3</b>	<b>9.1%</b>	<b>10.6%</b>	<b>622.5</b>	<b>549.7</b>	<b>13.2%</b>	<b>15.6%</b>
Eastern Europe	54.7	48.4	12.9%	10.0%	156.2	141.0	10.8%	10.6%
Others Europe	70.7	57.6	22.7%	22.6%	198.4	185.5	7.0%	7.7%
<b>Other European countries</b>	<b>125.4</b>	<b>106.0</b>	<b>18.3%</b>	<b>16.8%</b>	<b>354.6</b>	<b>326.5</b>	<b>8.6%</b>	<b>8.9%</b>
<b>North America</b>	<b>196.3</b>	<b>161.3</b>	<b>21.7%</b>	<b>16.6%</b>	<b>557.3</b>	<b>439.3</b>	<b>26.8%</b>	<b>19.4%</b>
Asia	65.5	56.5	15.9%	14.6%	170.5	150.8	13.1%	11.7%
Other countries in the Rest of the world	59.7	50.8	17.5%	16.2%	169.4	154.1	9.9%	9.3%
<b>Rest of the World</b>	<b>125.2</b>	<b>107.3</b>	<b>16.7%</b>	<b>15.4%</b>	<b>339.9</b>	<b>304.9</b>	<b>11.5%</b>	<b>10.5%</b>
<b>Group Sales</b>	<b>644.7</b>	<b>555.9</b>	<b>16.0%</b>	<b>14.5%</b>	<b>1,874.3</b>	<b>1,620.4</b>	<b>15.7%</b>	<b>14.3%</b>

Sales in **Major Western European countries** reached €622.5 million, up 15.6% year-on-year. Over the period, sales in Major Western European countries represented 33.2% of total Group sales, compared to 33.9% in 2018.

**France** – Sales reached €240.1 million, up 18.7% year-on-year, driven by the continued Cabometyx ramp-up, sustained growth of Somatuline and Decapeptyl, as well as the contribution of Onivyde sales to Ipsen's new ex-U.S. partner since September 2018.

**Germany** – Sales reached €141.7 million, up 17.4% year-on-year, driven by Cabometyx supported by the launch in first-line renal cell carcinoma (RCC) and second-line hepatocellular cell carcinoma (HCC) and the continued solid volume growth of Somatuline.

**Italy** – Sales reached €87.8 million, up 11.7% year-on-year, mainly driven by the double-digit growth of Decapeptyl and Somatuline and a solid performance of Cabometyx.

**Spain** – Sales reached €77.1 million, up 16.2% year-on-year, driven by the increasing contribution from Cabometyx and the strong growth of Somatuline.

**United Kingdom** – Sales reached €75.9 million, up 7.5% year-on-year, driven by the strong performance of Somatuline and Decapeptyl.

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Sales in **Other European countries** reached €354.6 million, up 8.9% year-on-year, driven by the launch of Cabometyx in certain countries, the strong growth of Somatuline and the continued solid performance of Dysport. Over the period, sales in the region represented 18.9% of total Group sales, compared to 20.1% in 2018.

Sales in **North America** reached €557.3 million, up 19.4% year-on-year driven by continued strong demand growth of Somatuline, steady growth of Onivyde and Dysport and the contribution of the launch of Cabometyx in Canada. Over the period, sales in North America represented 29.7% of total Group sales compared to 27.1% in 2018.

Sales in the **Rest of the World** reached €339.9 million, up 10.5% year-on-year, driven by Cabometyx launches in some countries and the good performance of Decapeptyl partly offset by lower Consumer Healthcare sales in Algeria and China. Over the period, sales in the Rest of the World represented 18.1% of total Group sales compared to 18.8% in 2018.